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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,646	06/28/2005	Robert Nitsch	2958-131	1021

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/527,646	NITSCH ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *3-20 and 22-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/EP03/010228 filed on 9/15/2003.

The preliminary amendment filed on 03/14/2005 amending claims 3, 6-8, 10, 12-15, 19-21, 23 and newly adding claims 25-29 is acknowledged. Claims 1-29 are pending.

In the previous office action mailed on 12/1/2005 in the requirement for restriction, the examiner left unexplained about the invention between Groups (A)-(L) comprising patentably distinct the nucleic acid and proteins. The nucleic acid and proteins of Group (A)-(L) are unrelated. In the instant case the different nucleotides encoding proteins of Group (A)-(L), which are polypeptides having lipid phosphate phosphatase (LPP) activity, do not have special technical feature among each other because they all represent structurally different polypeptides and polynucleotide encoding them. As mentioned in the previous office action, a DNA encoding a polypeptide having lipid phosphate phosphatase (LPP) activity is known in the art and does not make contribution over the prior art. Therefore, they all lack special technical feature.

Applicant's election without traverse of Group I claims 1-2 and 21 and SEQ ID NO: 1 as a protein species in the communication filed on 12/30/2005 is acknowledged. Claims 3-20 and 22-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-2 and 21 are at issue and are present for examination.

Claim Objections

Claim 1 is objected to because of the recitation "Isolated protein" should be "An isolated protein". Appropriate correction is required.

Claim 2 is objected to because of the recitation "protein according" should be "The protein according". Appropriate correction is required.

Claim 21 is objected to because of the recitation "Pharmaceutical composition" should be "A pharmaceutical composition". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite and vague in the recitation of the "substantially the same amino acid sequence " as it is unclear how similar to SEQ ID NO: 1, a sequence must be to be encompassed by the phrase "substantially the same amino acid sequence".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of protein molecules substantially similar to SEQ ID NO: 1 or a splice variant or a salt thereof. The specification does not contain any disclosure of the function of all proteins substantially the same as SEQ ID NO: 1 or a splice variants or a salts

thereof. The genus of proteins recited comprise is a large variable genus with the potentiality of encoding many different proteins, variants or mutants. Therefore, many functionally unrelated proteins are encompassed within the scope of these claims. The specification discloses only several species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-2 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein of SEQ ID NO: 1, does not reasonably provide enablement for any protein substantially the same as SEQ ID NO: 1or any splice variant of the SEQ ID NO: 1 or all fragments of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1 and 2 are so broad as to encompass any protein having substantially the same amino acid sequence as SEQ ID NO: 1 or any splice variant of the SEQ ID NO: 1 or fragments thereof, while claim 21 recites a composition comprising these polypeptides for the treatment of neuronal injuries or diseases. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural

and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only several proteins.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all proteins substantially the same as SEQ ID NO: 1 or any splice variant or fragment thereof because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting LPP activity; (B) the general tolerance of LPP to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any LPP residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any protein substantially the same as SEQ ID NO: 1 or any splice variant thereof. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any LPP proteins having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Brauer et al. ("A new phospholipid phosphatase, PRG-1, is involved in axon growth and regenerative sprouting", Nat Neurosci 2003 Jun; 6(6): 572-8, see IDS). Brauer et al. disclose a new membrane-associated lipid phosphate phosphatase which is about 99% identical to the SEQ ID NO: 1 of the is instant application, named plasticity-related gene 1 (PRG-1), which facilitates axonal outgrowth during development and regenerative sprouting. Brauer et al. also disclose that PRG-1 is specifically expressed in neurons and is located in the membranes of outgrowing axons and acts as an ecto-enzyme and attenuates phospholipid-induced axon collapse in neurons and

facilitates outgrowth in the hippocampus. Brauer et al. further propose a novel mechanism by which axons are able to control phospholipid-mediated signaling and overcome the growth-inhibiting, phospholipid-rich environment of the extracellular space during development, after lesions and following brain injury.

Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg et al. (UniProt Accession No. Q86XM6_human, LPPR4 protein", created on 7/1/2003). Strausberg et al. disclose a human protein isolated from human brain, which is 98% identical to, the to the protein of SEQ ID NO: 1 of the instant application.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Isogai et al. (UniProt/EMBL Accession No. Q96MP0_human, created on 12/1/2001). Isogai et al. disclose a human protein sequence isolated from human brain, which is 77% identical to the SEQ ID NO: 1 of the instant application and weakly similar to phosphatidic acid phosphatase 2a (PAP2a). Since 77% homology is within the scope of "substantially the same" to SEQ ID NO: 1, therefore, Isogai et al. anticipates instant claims.

Conclusion

Status of the claims:

Claims 1-2 and 21 are pending.

Claims 1-2 and 21 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

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